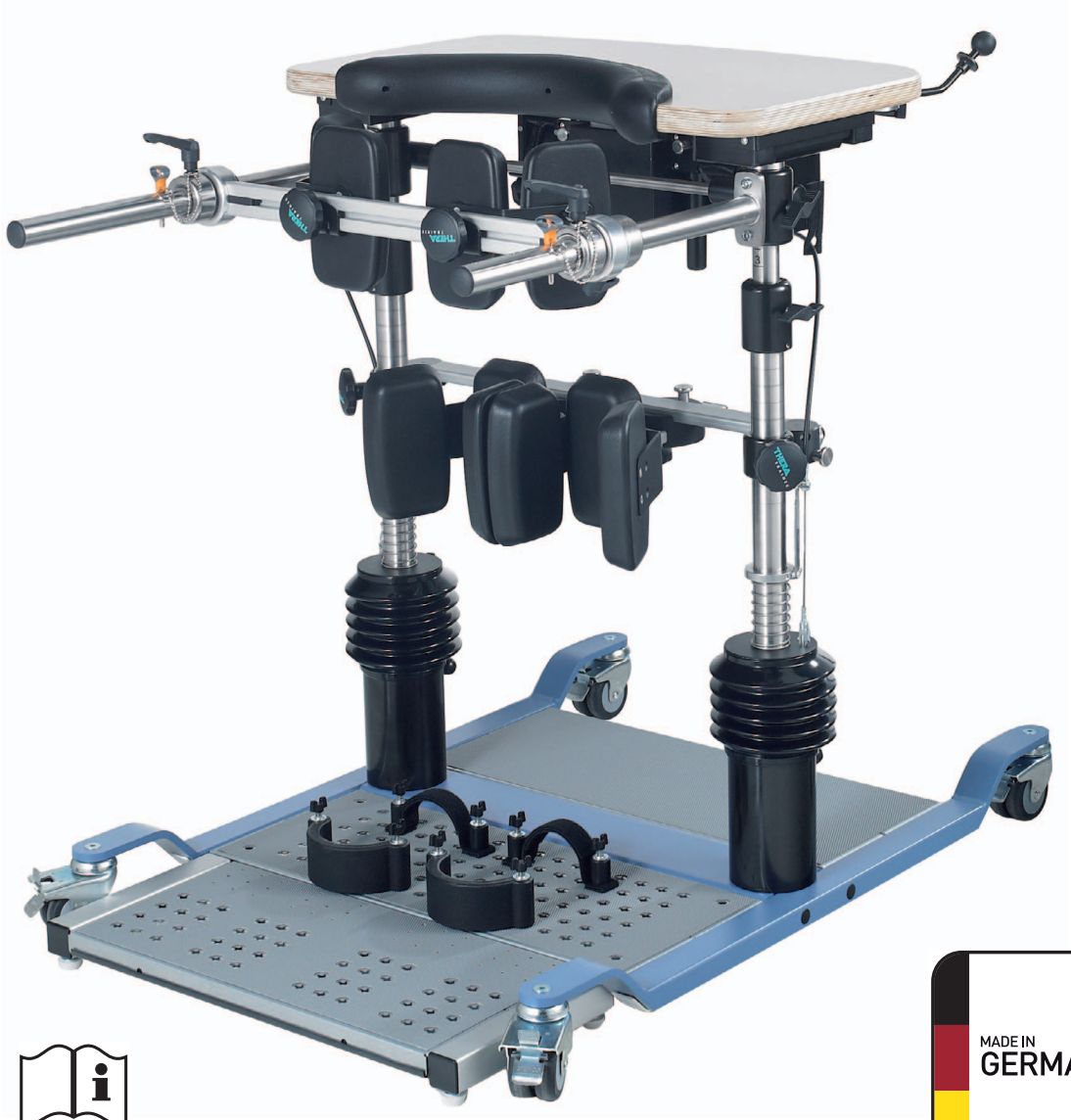
THERA TRAINER

THERA-TRAINER BALO (≙ BALANCE-TRAINER)

USER MANUAL

EN English translation of original user manual



MADE IN GERMANY

Congratulations!

Opting for a THERA-Trainer was a great choice. This innovative movement exerciser offers top performance „Made in Germany“.

This user manual will help you get to know your THERA-Trainer better. It will safely guide you through all functions and control options and provide you with tips and information on how to use your new exerciser best.

Before starting the unit for the first time, please read and observe chapter 2 “Safety and dangers”.

Should you have any questions or suggestions, your local specialist dealer will be happy to help.

Have fun and get moving with your THERA-Trainer.

1 USER GUIDE 4
1.1 Warning notices 4
1.2 Notes 4
1.3 Symbols in the user manual 4
1.4 Symbols on the product 5
2 SAFETY AND DANGERS 6
3 INTENDED USE 7
3.1 Indications 7
3.2 Biocompatibility 7
4 FORESEEABLE MISUSE 7
4.1 Contraindications 8
4.2 Misuse 8
5 SCOPE OF DELIVERY AND DESCRIPTION OF DE-LIVERED EQUIPMENT 9
5.1 Scope of delivery 9
5.2 Basic equipment 9
5.3 Options 9
6 OVERVIEW 10
7 START-UP 11
7.1 Unpacking 11
7.2 Installation of THERA-Trainer balo 11
7.3 Transport of THERA-Trainer balo 13
8 OPERATION 14
8.1 Preparation for training 14
8.2 Safety devices 24
9 CONTROL 25
9.1 Control elements 25
9.2 Electric lift 25
9.3 Lifting and lowering without electric lift 28
9.4 Starting up the control and display unit 29
10 CLEANING AND DISINFECTION 31
11 MAINTENANCE AND REPAIR 32
11.1 Replacing the balance unit 32
11.2 Replacing the patient belt with leg straps and bottom enlarged 32
11.3 Replacing the fuse 32
11.4 Further use 32
12 TECHNICAL DATA 33
13 STANDARDS AND LAWS 33
14 DISPOSAL 33
15 NOTES ON ELECTROMAGNETIC COMPATIBILITY 34
15.1 Lines, line lengths and accessories 34
15.2 Warning notice regarding installation 34
15.3 Level of conformity 34
15.4 Electromagnetic emission 34
15.5 Immunity 35
15.6 Recommended protective distances between portable and mobile HF telecommunication devices and THERA-Trainer balo 37
16 WARRANTY 37

1 USER GUIDE

User manual and product are labelled with symbols. The symbols and their functions make it easier to use the product safely and efficiently.

1.1 Warning notices

Classification of warning notices

There are different types of warning notices indicated by the following signal words depending on the type of danger:

- ❑ **Caution** warns about the risk of material damage.
- ❑ **Warning** warns about the risk of physical injury.
- ❑ **Danger** warns about the risk of fatal injury.

Structure of warning notices

Signal words

Type and source of danger!

▶ Action to avoid the danger.

1.2 Notes

Note *Information on the efficient use of the product.*

1.3 Symbols in the user manual

Instructions

Structure of instructions:

▶ Instruction to do something.

Result of the action, if necessary.

Lists

Structure of bulleted lists:

- ❑ List level 1
  - – List level 2

Structure of numbered lists:

1. List level 1
2. List level 1
   - 2.1 List level 2
   - 2.2 List level 2

1.4 Symbols on the product

	User manual
	Observe the user manual!
	Manufacturer
	Date of manufacture
	Market launch according to directive 93/42 EEC for medical devices
	Serial number
	Type BF medical device
	Disposal Do not dispose of product with the regular household waste. Dispose of product in accordance with local regulations.
	Protect product from humidity.
	Maximum body weight

2 SAFETY AND DANGERS

- Observe the user manual.
- Use THERA-Trainer balo exclusively in good and functional condition.
- Regularly check tightness of screws.
- Prior to the initial start-up, have your trained dealer, doctor or therapist show you how to use the product.
- Put THERA-Trainer balo on even and slip-proof floor.
- Keep sufficient distance between THERA-Trainer balo and any walls and obstacles.
- Always wear closed shoes when training (both user and assistant).
- Always use THERA-Trainer balo with knee support set and pelvic support set.
- Before getting in, make sure that all transport castors with brake are blocked.
- Block balance function before getting in.
- Exercise exclusively under supervision of a trained assistant.
- Do not use THERA-Trainer balo in wet, humid or hot environments.
- Have exclusively trained dealers do any repair or maintenance work.
- In case of damage, malfunctions, etc. of the THERA-Trainer balo, contact a trained dealer immediately.
- Consult the manufacturer before any modification and modify THERA-Trainer balo exclusively with the manufacturer's approval.
- Disinfect THERA-Trainer balo before every training.
- Do not smoke while exercising.
- Make sure that THERA-Trainer balo does not get wet.
- Do not use THERA-Trainer balo to transport persons.
- If any symptoms of illness occur during or after training, seek medical advice immediately.
- Make sure that buckle tongues audibly click into place in belt buckles.
- Make sure that SAFETY-STOP button is easily accessible for user and trained assistant at all times.
- When laying cables, make sure that
  - the user's movements are not limited.
  - the movements of the THERA-Trainer balo are not limited.
  - there is no risk of persons falling over or being limited by cables.
- Use the manufacturer's original parts exclusively.
- Use THERA-Trainer balo and battery charger exclusively with undamaged and functional cables.
- Take care not to pinch any fingers when adjusting settings (e. g. height of table unit) on THERA-Trainer balo.
- Electric lift of THERA-Trainer balo:
  - use exclusively with correctly set supply voltage.
  - do not use continuously (maximum 10 lifts within 5 minutes when loaded, then let it cool down for 10 minutes).
  - use exclusively with the fuses indicated in technical data.
  - use exclusively with accessory patient belt with leg straps and bottom enlarged.
  - use exclusively with pelvic support set.
- Before using the electric lift, check if patient belt with leg straps and bottom enlarged is correctly fastened.
- Before using the THERA-Trainer balo, check if pelvic support set and knee support set are correctly fastened.

- ▶ Before every training, make sure that safety equipment is working correctly.
- ▶ Before every training, make sure that balance unit is working correctly.
- ▶ Keep animals and playing children away from THERA-Trainer balo.
- ▶ Set spring resistance of THERA-Trainer balo to fit the user's activity, body size and body weight.

3 INTENDED USE

The THERA-Trainer balo is an indoor therapy device for supervised indoor use only.

The THERA-Trainer balo helps the user to stand dynamically or maintain a vertical (or nearly vertical) position by:

- ❑ Verticalisation
- ❑ Tone regulation
- ❑ Improving balance (with fall prophylaxis).
- ❑ Maintaining or prolonging the supporting leg phase.
- ❑ Preventing muscular atrophy.
- ❑ Strengthening existing musculature.
- ❑ Stabilising the hip joint.
- ❑ Improving upper body stability.
- ❑ Activating or stabilising the circulation.
- ❑ Activating or stabilising the metabolism.
- ❑ Contracture prophylaxis

Note

The THERA-Trainer balo is a medical device. The intended use includes the treatment as a medical device.

3.1 Indications

The THERA-Trainer balo is suitable for users with congenital or acquired restrictions or loss of their ability to stand (e.g. for stroke patients, elderly patients, or persons with multiple sclerosis, Parkinson's disease, muscular diseases or paraplegia). The THERA-Trainer balo enables users to get out of their wheelchairs safely, with or without help depending on the user's condition.

The THERA-Trainer balo is suitable for users with balance or coordination problems while standing.

Minimum requirement:

- ❑ the user's lower extremities are able to support his full weight.

To stand in the THERA-Trainer balo without assistance:

- ❑ The user is able to actively straighten his upper body.

If the user is able to control the THERA-Trainer balo without assistance:

- ❑ Make sure that a trained assistant supervises the training.

3.2 Biocompatibility

All components and options of the THERA-Trainer balo the user will touch when using the unit as intended are designed to meet the biocompatibility requirements of the applicable standards.

- ▶ For any questions, contact a trained dealer.

4 FORESEEABLE MISUSE

The THERA-Trainer balo is not suitable for:

- ❑ Diagnosis
- ❑ Monitoring
- ❑ Measuring

4.1 Contraindications

Do not use THERA-Trainer balo for:

- ❑ users weighing more than 140 kg.
- ❑ users shorter than 120 cm (with balance unit short).
- ❑ users taller than 160 cm (with balance unit short).
- ❑ users shorter than 150 cm (with balance unit long).
- ❑ for users taller than 200 cm (with balance unit long).
- ❑ users with serious contractures.
- ❑ users with ulcers or raw skin that would touch the unit (if in doubt, seek medical advice).
- ❑ users with extreme osteoporosis.
- ❑ users with imperfect osteogenesis (Osteogenesis imperfecta).
- ❑ users with unstable circulation,
  - e. g. due to being bedridden.
- ❑ users with limited exercise tolerance of their lower extremities.
- ❑ outdoor exercise.
- ❑ transport (e. g. of the user).
- ❑ unsupervised training.

4.2 Misuse

Do not use THERA-Trainer balo in:

- ❑ combination with other products emitting ionising radiation (e. g. radiation therapy, nuclear medicine, etc.)
- ❑ rooms containing
  - explosive substances
  - oxygenated air
- ❑ the presence of
  - flammable anaesthetics
  - volatile solvents

5 SCOPE OF DELIVERY AND DESCRIPTION OF DELIVERED EQUIPMENT

The THERA-Trainer balo comes with individual options. This user manual describes all options available for the THERA-Trainer balo.
Depending on the model, the user manual may include options not featured by the THERA-Trainer balo.
If the THERA-Trainer balo features options not described in the user manual, an appendix will be included.

5.1 Scope of delivery

The delivery note contains all necessary information on the scope of delivery.

5.2 Basic equipment

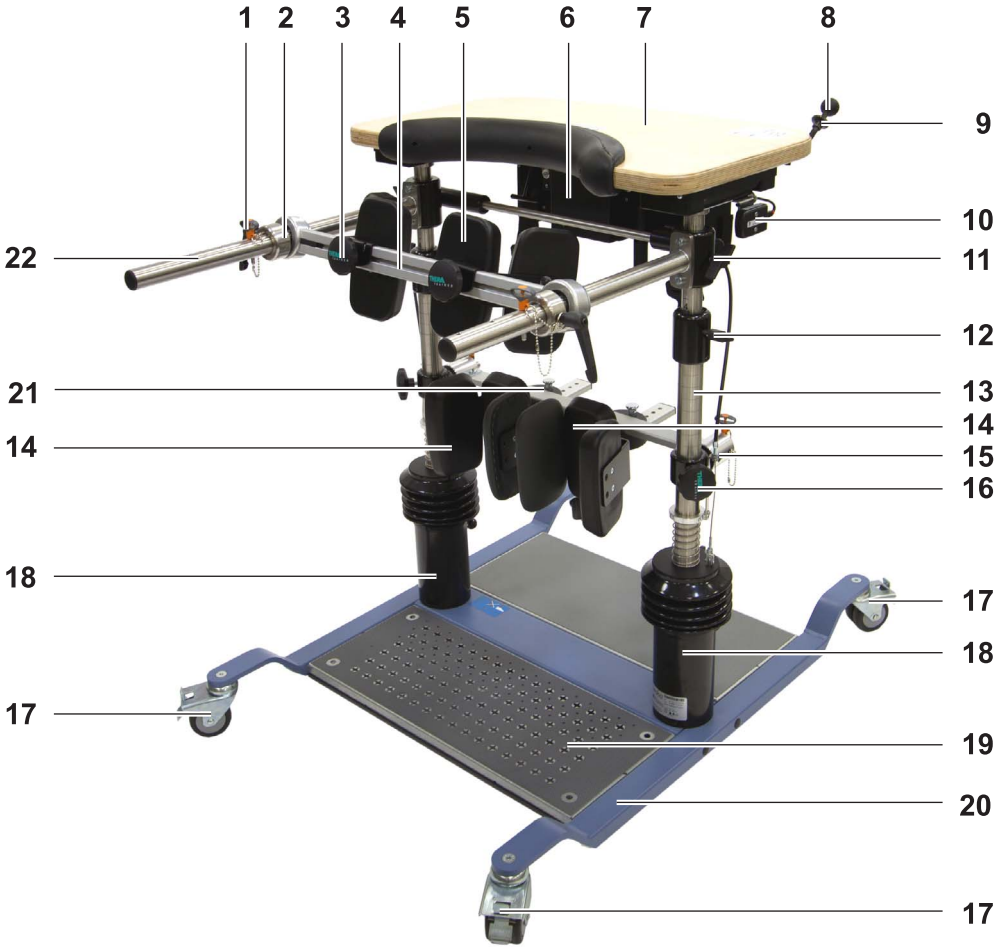
- ❑ Base unit
  - – Powder-coated metal pipe frame
  - – Transport castors with brake (blockable)
- ❑ Tread unit
  - – Metal tread with holes for variable positioning of foot fixing
  - – Wear-resistant anti-slip mat
  - – Forefoot securing system
- ❑ Balance unit
- ❑ Knee support set in different sizes
- ❑ Pelvic support set
- ❑ Hand/arm fixing
  - – Handrail, adjustable in height
  - – Table unit
- ❑ User manual THERA-Trainer balo

5.3 Options

Available options:

- ❑ Tread extension
- ❑ Tread enhancement
- ❑ Forefoot quick securing system
- ❑ Quick securing system for heels
- ❑ Knee support lowering
- ❑ Knee support set in different sizes
  - – small, knee width up to approx. 10 cm
  - – normal, knee width up to approx. 12 cm
  - – wide, knee width up to approx. 14 cm
- ❑ Center cushion for pelvic support set
- ❑ Electric lift
  - – Main cable
  - – SAFETY-STOP button
- ❑ Patient belt with leg straps and bottom enlarged in different sizes
  - – size S, abdominal girth 85-106 cm
  - – size M, abdominal girth 91-114 cm
  - – size L, abdominal girth 104-130 cm
  - – size XL, abdominal girth 117-146 cm
- ❑ Cushion for arm rest
- ❑ Upper body support
- ❑ Center cushion
- ❑ Control and display unit with 23’’ colour screen incl. touch function, in combination with:
  - – Mobile holder for control and display unit
- ❑ Control and display unit with 10.4" colour screen incl. touch function, in combination with:
  - – Table holder for control and display unit
- ❑ Software package Balancing individual therapy
- ❑ Position sensor

6 OVERVIEW



(1) Ball catch pin
(2) Retaining ring for pelvic support set
(3) Star-shaped handle for pelvic support
(4) Pelvic support set
(5) Pelvic support
(6) Electric lift
(7) Table unit
(8) Release lever for balance function
(9) Locking ring for balance function
(10) Position sensor
(11) Height adjustment for handrails
(12) Height adjustment of table unit
(13) Vertical pipe of balance unit
(14) Knee support
(15) Securing system for knee support set
(16) Height adjustment for knee support set
(17) Transport castors with brake
(18) Balance unit with settings for spring resistance
(19) Tread unit
(20) Base unit
(21) Knee support set
(22) Handrail

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Version: 04/2013

7 START-UP

7.1 Unpacking

Unpack THERA-Trainer balo:

- ▶ Remove THERA-Trainer balo from packaging.
- ▶ Check THERA-Trainer balo incl. all accessories/options for transport damage.
- ▶ Check if delivery is complete.
- ▶ Inform supplier or forwarding agent immediately about any damage.
- ▶ Make sure that voltage supply matches voltage of electric lift.

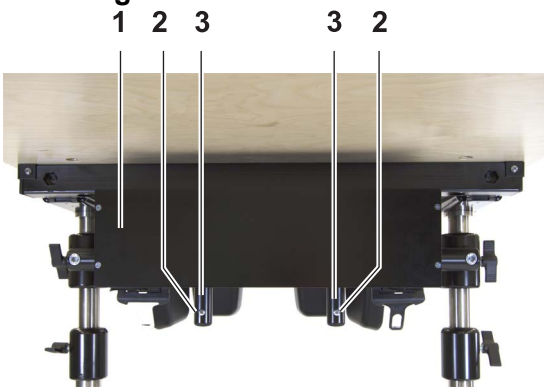
7.2 Installation of THERA-Trainer balo

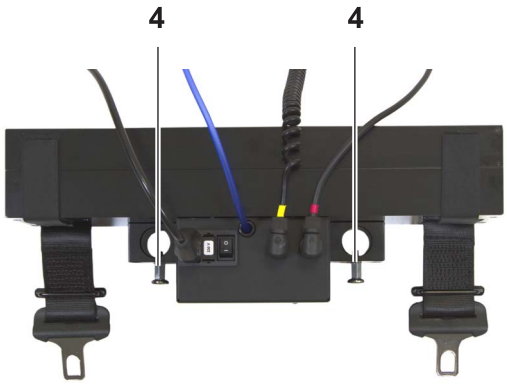
Caution

Short-circuit due to incorrect installation!

- ▶ Observe colour code of circular connectors.
- ▶ Make sure that cable and circular connectors are dry for the installation.

Installing the electric lift





Components:

- ❑ Motor unit with belt straps
- ❑ Main cable
- ❑ Control unit with connecting cable
- ❑ Sip-and-puff hose
- ❑ SAFETY-STOP button with connecting cable

Installation:

- ▶ Remove safety screws **2**.
- ▶ Put electric lift **1** onto forearms.
- ▶ Pull out safety catches **4**.
- ▶ Slide electric lift the right way around onto fixture pipes **3**.
- ▶ Make sure that safety catch audibly clicks into place.
- ▶ Tighten safety screws.

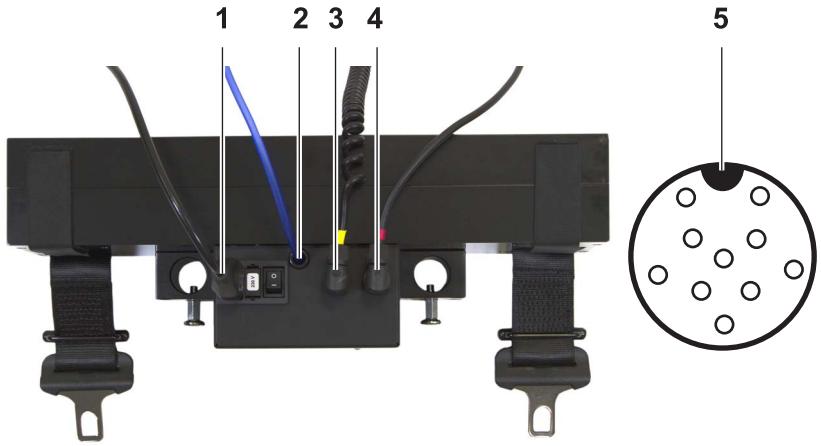
It is possible to adjust the height of the electric lift.

Connecting cables

Caution

Material damage due to incorrect installation!

- ▶ Make sure that circular connector is plugged in correctly when connecting cables.
- ▶ Observe position of plug.
- ▶ Make sure that circular connectors are secured.



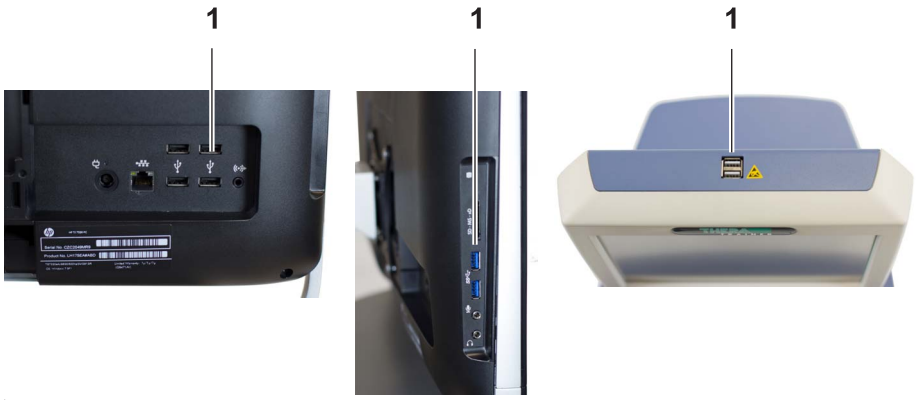
- ▶ Plug power supply cord into port **1** on motor housing.
- ▶ Plug helix cable of control unit into yellow port on motor housing **3** and use the screw to secure it (observe position of plug **5**).
- ▶ Plug cable of SAFETY-STOP button into red port on motor housing **4** and use the screw to secure it (observe position of plug **5**).
- ▶ Put the SAFETY-STOP button in a place where the user can reach it (e.g. on the table) and fasten it with velcro straps.
- ▶ If necessary, connect sip-and-puff hose of sip-and-puff-control to connection nipples on motor housing **2**.

Connecting the position sensor

Caution

Material damage due to incorrect installation!

- ▶ Make sure that USB cable is correctly plugged in.



- ▶ Plug USB cable of position sensor into USB interface **1** of control and display unit.
- ▶ The USB interfaces are located on rear, side or top of the control and display unit.
- ▶ Observe the enclosed user manual.

7.3 Transport of THERA-Trainer balo

Warning

Risk of injury due to incorrect transport!

- ▶ Do not use THERA-Trainer balo for training in transport condition.
- ▶ Never use THERA-Trainer balo to transport users.

- ▶ Use exclusively transport castors with brake for moving the THERA-Trainer balo.
- ▶ Before any transport, make sure that
  - – THERA-Trainer balo is standing on transport castors with brake.
  - – balance function is locked.

8 OPERATION

8.1 Preparation for training

Warning

Risk of injury due to insufficient preparation!

- ▶ Before starting any exercise, make sure that balance unit is intact and working correctly.
- ▶ Make sure that patient belt with leg straps and bottom enlarged is intact (e.g. no defective seams).
- ▶ Make sure that patient belt with leg straps and bottom enlarged is correctly positioned and and safely connected to the buckles.
- ▶ Make sure that pelvic support set is correctly fastened.
- ▶ Disinfect THERA-Trainer balo before every training (see 10 Cleaning and disinfection).

Note

Height markings on table unit, knee supports and handrails make it easy to change horizontal settings.
Before every training session, adjust settings of THERA-Trainer balo to match the user's individual needs.

Locking transport castors with brake

Prevent THERA-Trainer balo from moving as follows:

- ▶ Before every training session, lock all four transport castors with brake.
- ▶ Push down locking lever on transport castors with brake.

Releasing transport castors with brake

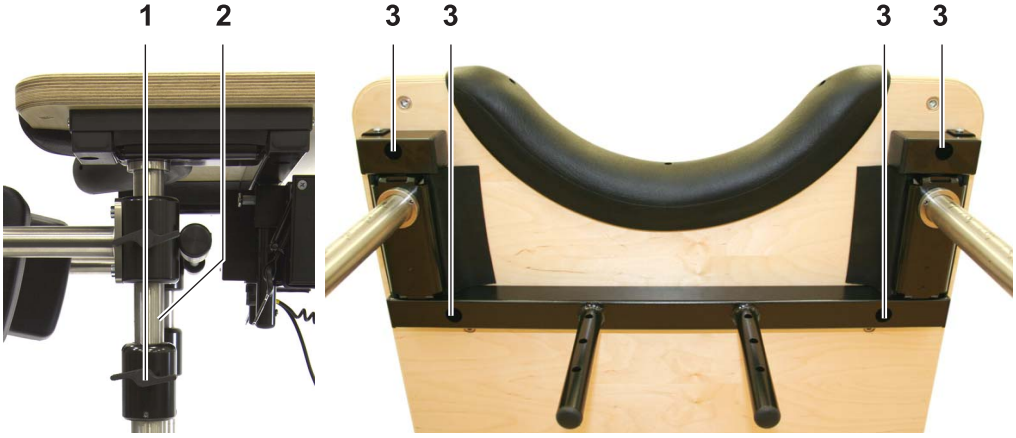
To transport THERA-Trainer balo:

- ▶ Release locking lever on transport castors with brake.

Adjusting the table unit

Note

A pneumatic spring supports the height adjustment.



Setting the height of the table unit:

- ▶ Loosen winged screw **1** on first vertical pipe.
- ▶ Set height using marks **2**.
- ▶ Tighten winged screw on vertical pipe.
- ▶ Set height on second vertical pipe.
- ▶ Make sure that height settings of left and right vertical pipe of table unit are the same.

Setting the horizontal position of the table unit:

There are three possible pre-set positions.

- ▶ Set horizontal position of table unit to suit the user's build.
- ▶ Loosen four retaining screws **3** (Allen key 5 mm) on underside of table unit.
- ▶ Keep table from dropping with the help of a second person.
- ▶ Position table unit as required.
- ▶ Tighten four retaining screws.

Adjusting the handrails

- ▶ Make sure that handrails are easily accessible during the training session.

Adjusting the handrails:

- ▶ Loosen winged screw **1** on first vertical pipe.
- ▶ Set height using marks **2**.
- ▶ Tighten winged screw on vertical pipe.
- ▶ Set height on second vertical pipe.
- ▶ Make sure that height settings of left and right vertical pipe are the same.

Adjusting the knee support set

Warning

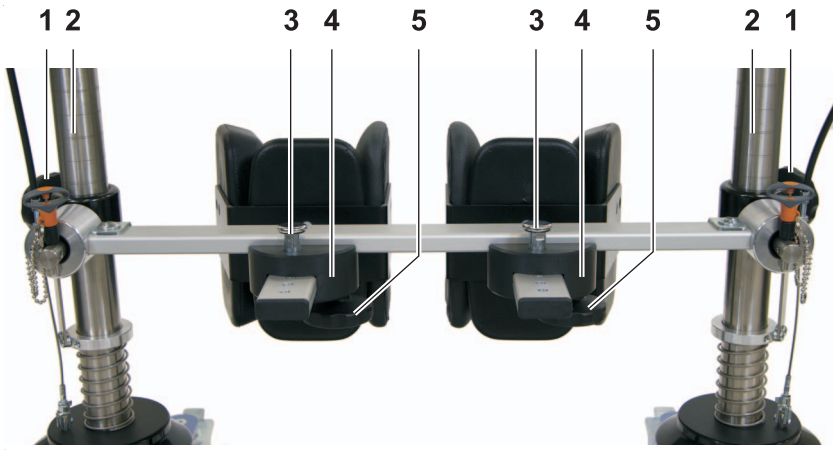
Risk of injury due to incorrectly adapted knee support!

- ▶ Prior to every training session, adapt knee support to the user's individual needs.
- ▶ Adjust knee support so as to prevent overextension of joints and damage to muscles, tendons or ligaments.

Note

Use THERA-Trainer balo exclusively with knee support set.

The knee support set safely supports the user when rising, standing and sitting down. Adjusting the knee support set does not require any tools.



- ▶ Position user in wheelchair in front of THERA-Trainer balo.
- ▶ Select knee support size (small, normal, wide) to fit knee width.

Setting the height:

- ▶ Loosen star-shaped handle **1** on first vertical pipe.
- ▶ Set height using marks **2**.
- ▶ Tighten star-shaped handle on vertical pipe.
- ▶ Set height on second vertical pipe.
- ▶ Make sure that height settings of left and right vertical pipe are the same.

Setting the depth:

- ▶ Set depth of knee supports individually to obtain the required flexion or extension.
- ▶ Pull out safety catch **3** of knee support.
- ▶ Position knee support as required (6 pre-set positions).
- ▶ Release safety catch.
- ▶ Make sure that safety catch audibly clicks into place.

Setting the distance:

- ▶ Set knee supports so that the distance between them corresponds to distance between the user's opened knees.
- ▶ Loosen star-shaped handle **5** on underside of knee support.
- ▶ Adjust distance of knee support to fit the user's individual needs.
- ▶ Tighten star-shaped handle.
- ▶ Make sure that distance is the same on left and right knee support.

Removing a single knee support:

- ▶ Remove knee support before user is standing in THERA-Trainer balo.
- ▶ Pull out safety catch **3** of knee support.
- ▶ Pull knee support out of securing system **4**.
- ▶ Make sure that user is able to maintain upright standing position safely and without assistance.
- ▶ Never remove both knee supports at the same time.

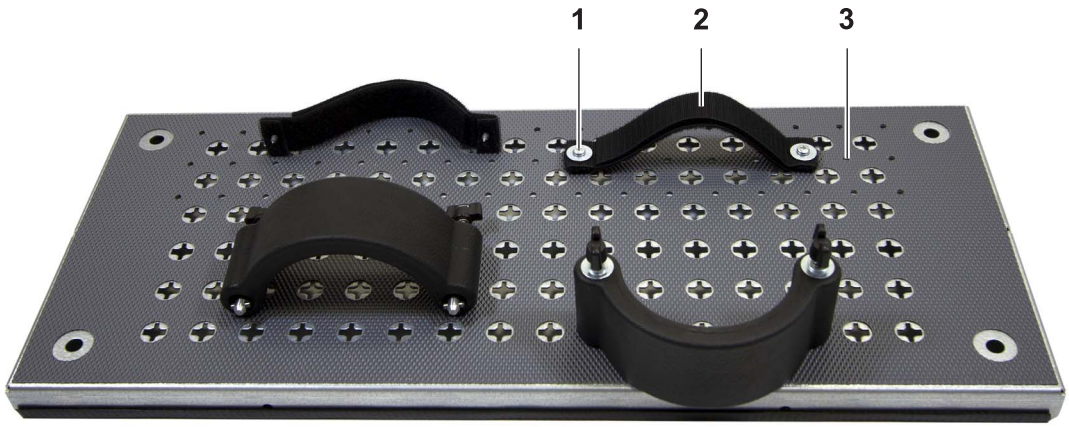
Lowering the knee supports:

It is possible to lower the knee supports by 60 mm.

- ▶ Observe extra service instructions.

Adjusting the forefoot securing system

The forefoot securing system secures the feet on the tread with Velcro straps.



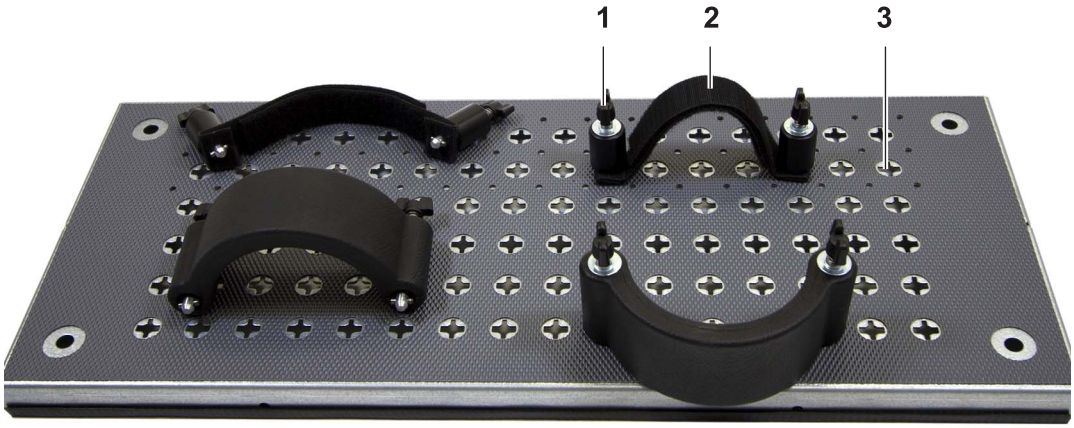
- ▶ Find the optimal position for the user's feet on the quick securing system for heels on the tread of the THERA-Trainer balo.

Adjusting the forefoot securing system:

- ▶ Put screws **1** on both forefoot securing systems **2** into small holes **3** and tighten them.
- ▶ Secure the user's feet on treads with velcro straps.
- ▶ Before every training session, check if forefoot securing systems are correctly secured.

Adjusting the forefoot quick securing system

The forefoot quick securing system secures the feet on the tread with Velcro straps.

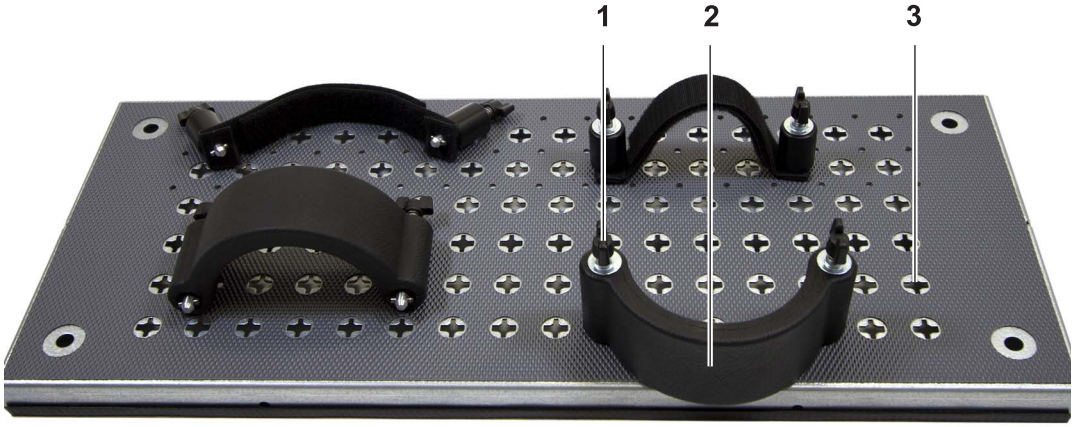


▶ Find the optimal position for the user's feet on the quick securing system for heels on the tread of the THERA-Trainer balo.

Adjusting the forefoot quick securing system:

▶ Push down winged screw **1** on both forefoot quick securing systems and turn them by 90°.
▶ Remove forefoot quick securing systems **2** and position them individually in the holes **3**.
▶ Press down winged screw and turn it by 90°.
▶ Secure the user's feet on treads with velcro straps.
▶ Before every training session, check if forefoot quick securing systems are correctly secured.

Adjusting the quick securing system for heels



▶ Position the user's feet on the tread of THERA-Trainer balo.

Adjusting the quick securing system for heels:

▶ Push down winged screw **1** on both quick securing systems for heels and turn them by 90°.
▶ Remove quick securing systems for heels **2** and position them individually in the holes **3**.
▶ Press down winged screw in holes and turn it by 90°.
▶ Before every training session, check if quick securing systems for heels are correctly secured.

Adjusting the pelvic support set

Warning

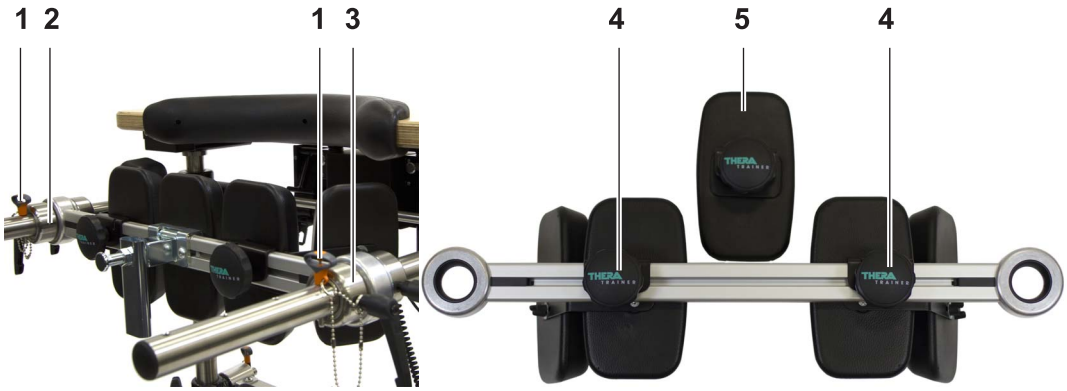
Danger of injury due to faulty fuse!

▶ Make sure that the ball catch pin goes completely through both holes when applying the pelvic support set.

Note

Use THERA-Trainer balo exclusively with pelvic support set.

The pelvic support set safely supports the user's pelvis on the sides and in the back.



▶ Apply the pelvic support set exclusively with the help of an assistant who is familiar with the process.

Applying the pelvic support set:

▶ The pelvic support set is pre-installed on the left-hand handrail.
▶ Bring the user into training position.
▶ Slide pelvic support set on right-hand handrail.
▶ Push pelvic support set onto the user's buttocks.
▶ Slide retaining ring **3** onto right-hand handrail until it reaches the pelvic support set.
▶ Fix retaining ring with clamping lever.
▶ Slide retaining ring **2** for left-hand handrail (already on left-hand handrail) up to pelvic support set.
▶ Fix retaining ring with clamping lever.
▶ For additional safety, put ball catch pins **1** on both handrails into the next free hole.
▶ Make sure that the ball catch pin goes completely through both holes.

The pelvic support set is perfectly secured.

Adjusting the width:

▶ Set pelvic supports to fit the width of the user's pelvis.
▶ Loosen star-shaped handle **4** on back of pelvic support.
▶ Set distance of pelvic support individually.
▶ Tighten star-shaped handle.

Adjusting the center cushion for pelvic support:

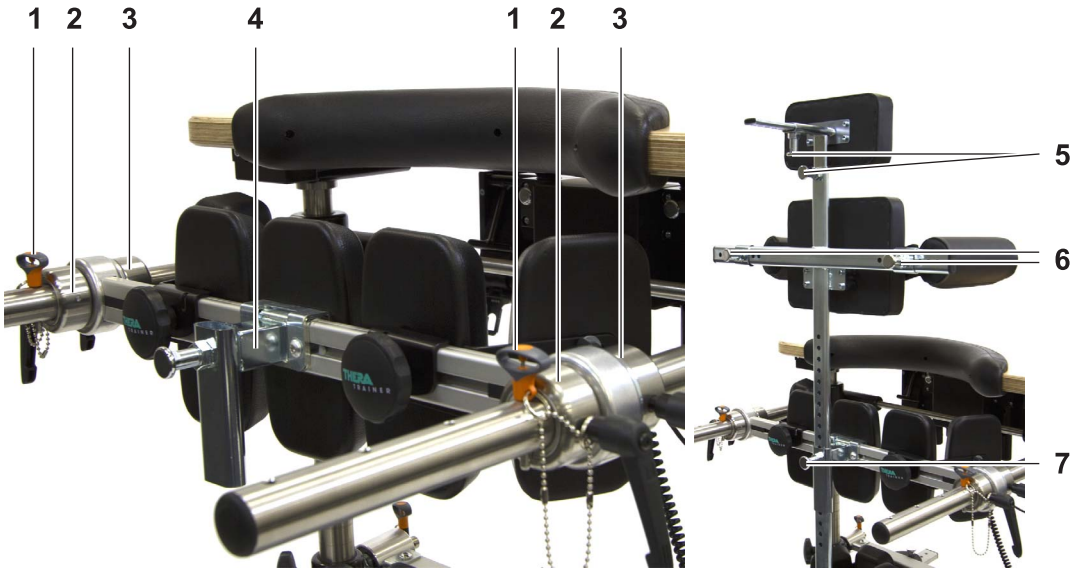
▶ Adjust center cushion **5** to provide additional pressure relief in the area of the lumbar spine and the coccyx.
▶ Use two center cushions at most.

Adjusting the upper body support

Note

The upper body support stabilises unstable upper bodies. It is possible to stabilise the users' unstable upper bodies to an optimum.

The upper body support consists of back, head and underarm cushions. Use upper body support exclusively in combination with pelvic support set.



Installing the securing system:

- ▶ Have a trained dealer carry out the installation.
- ▶ Install securing system **4** on pelvic support set.

Installing the pelvic support set:

- ▶ Have a trained dealer carry out the installation.
- ▶ Remove retaining screw on left-hand handrail (bottom) with a Phillips screwdriver.
- ▶ Remove retaining ring and pelvic support set.
- ▶ Slide first pair of retaining rings **3** (provided) on both handrails in front of the pelvic support set.
- ▶ Slide pelvic support set the right way around onto handrails.
- ▶ Slide second pair of retaining rings **2** on handrails.
- ▶ Screw retaining screw into left-hand handrail and tighten.

Securing the user:

- ▶ Loosen second pair of retaining rings **2** and remove retaining ring from right-hand handrail.
- ▶ Pull pelvic support set off right-hand handrail and fold it down on left-hand handrail.
- ▶ Position user in front of THERA-Trainer balo.
- ▶ Use table unit to support the user's upper body, have a second assistant support the upper body if necessary.
- ▶ Put a cushion under the upper body if necessary.
- ▶ Install the pelvic support set.
- ▶ For additional safety, put ball catch pins **1** on both handrails into the next free hole.
- ▶ When user is secured with pelvic support set, push upper body support into securing system.

Pushing the upper body support into the securing system:

- ▶ Pull out safety catch **7** on securing system.
- ▶ Push upper body support into securing system.
- ▶ Set height as required.
- ▶ Release safety catch.
- ▶ Make sure that safety catch audibly clicks into place.

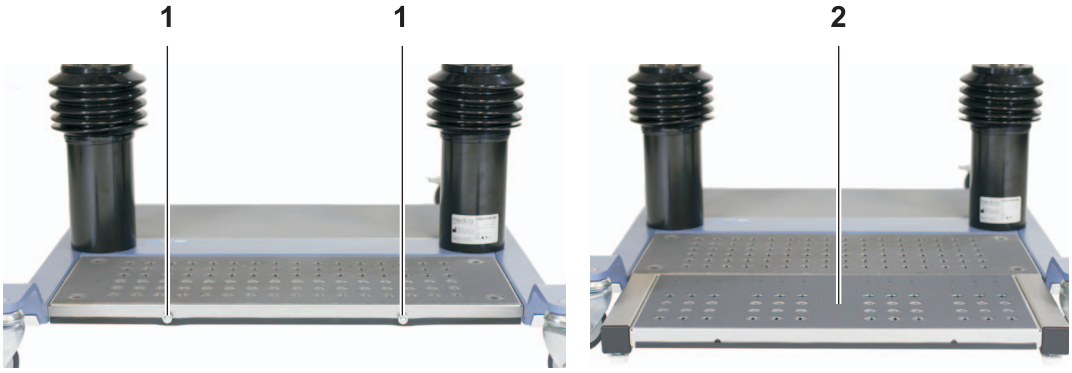
Applying the upper body support:

- ▶ Straighten the user into an upright position.
- ▶ Make sure that pelvic support set and the four retaining rings fastened tightly and without slack.
- ▶ Secure user with upper body support.
- ▶ Adjust cushions of upper body support with safety catches **5/6** to fit the user's needs.
- ▶ Adapt chest belt to the user's chest circumference.
- ▶ Secure user completely with upper body support.

Positioning arm support cushions

- ▶ If necessary, put an arm support cushion for the paretic arm on the table unit.
- ▶ If necessary, clean and disinfect arm support cushion.

Installing the tread extension



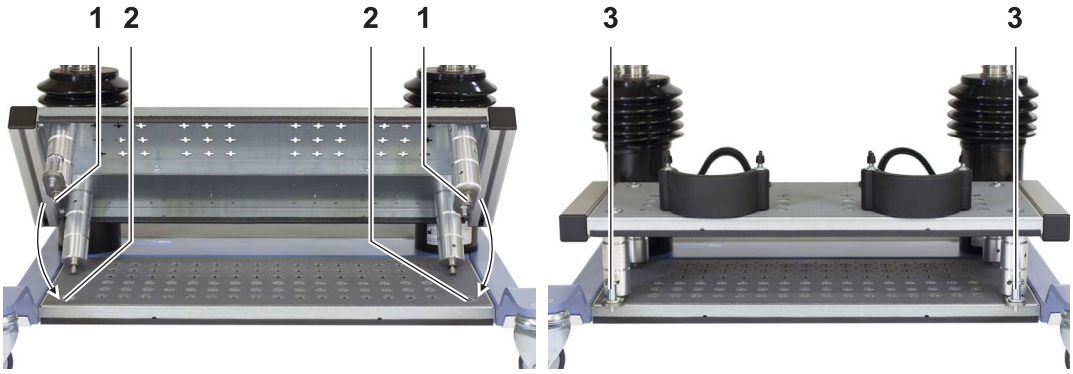
- ▶ Hook tread extension **2** into screws **1**.

Note

It is not possible to transport the THERA-Trainer balo once the tread extension is installed.

- ▶ Transport THERA-Trainer balo exclusively without tread extension.

Installing the tread enhancement



- ▶ Turn safety catch **3** to the front and pull it out.
- ▶ Put bolts **1** of tread enhancement into holes on tread **1**.
- ▶ Release safety catch.
- ▶ Adapt tread enhancement (e.g. foot fixing) to fit the user's needs.
- ▶ Observe enclosed service instructions.

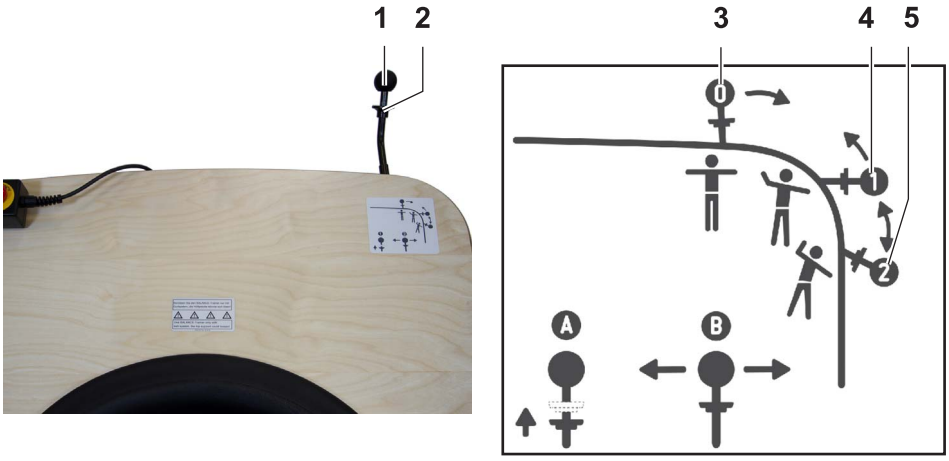
Setting balance function

Before every training session:

- ▶ Lift THERA-Trainer balo by table unit on left and right side.

If it is possible to remove the vertical pipe from the balance unit, then training with the THERA-Trainer balo is not allowed.

- ▶ Contact a trained dealer.



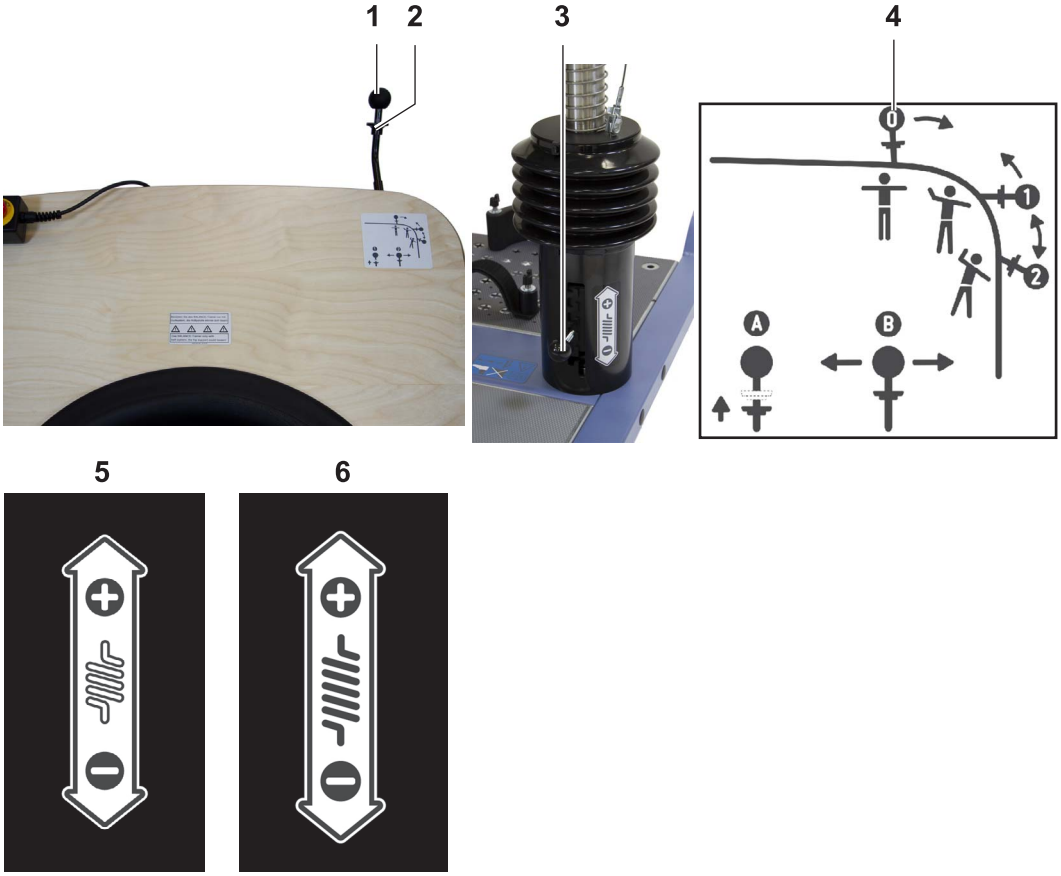
- ▶ Unlock release lever **1** by pulling locking ring **2**.
- ▶ Set release lever to 0, 1 or 2.
  - – Position 0 = balance function disabled **3.**
  - – Position 1 = balance function enabled with limited range of movement (up to 6°) **4.**
  - – Position 2 = balance function enabled with full range of movement (up to 11°) **5.**
- ▶ Release locking ring.
- ▶ Make sure that locking ring latches on.

Spring resistance settings

Warning

Risk of injury due to tipping over!

▶ Set spring resistance to fit the user's activity, body size and body weight.



▶ Unlock release lever **1** by pulling up locking ring **2**.
▶ Set release lever to 0 (**4**).
▶ Release locking ring.
▶ Make sure that locking ring latches on.
▶ Use lever **3** on balance unit to set spring resistance.
  – Down = low spring resistance
  – Up = high spring resistance
▶ Make sure that spring resistance is the same on left and right balance unit.
▶ Observe spring strength:
  – Sticker for low spring resistance **5**.
  – Sticker for high spring resistance **6**.

8.2 Safety devices

Warning

Risk of injury due to damaged safety equipment!

- ▶ Before every training, make sure that safety equipment is working correctly.
- ▶ In case of any malfunction, have the unit repaired by a trained dealer.

SAFETY-STOP button

After pressing SAFETY-STOP button **1**:

- ❑ Electric lift of THERA-Trainer balo stops.

To continue lifting or lowering the user:

- ▶ Check or eliminate danger.
- ▶ Unlock SAFETY-STOP button.
- ▶ Press arrow buttons on control unit of electric lift to continue lifting or lowering the user.

-or-

- ▶ Blow air into sip-and-puff hose of sip-and-puff system to continue lowering the user to a sitting position.
- ▶ Suck air out of sip-and-puff hose of sip-and-puff system to continue lifting the user.

Thermal circuit breaker

Function:

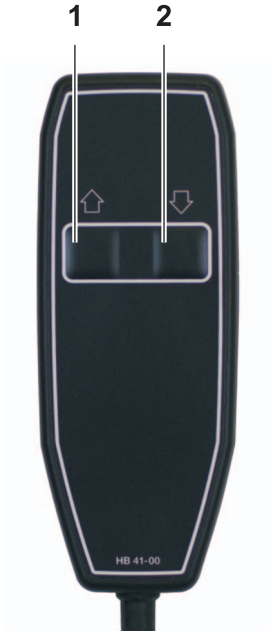
- ❑ protects electric lift from excess load (overheating)
- ❑ stops electric lift when it is constantly moving up and down

When the thermal circuit breaker has tripped:

- ❑ LED on electric lift lights up red.
- ❑ The only possible action is to lower the electric lift once.
- ❑ Lifting is only possible after the electric lift has cooled down (approx. 10 min.) and the LED on electric lift lights up green.

9 CONTROL

9.1 Control elements



(1) Button Arrow up
(2) Button Arrow down

Note *While in operation, always hold the control element as shown in the picture.*

Functions of control elements

Button Arrow up (1)
- ▶ Press and hold button: Belts of electric lift move upward.
- ▶ Release button: Electric lift stops lifting process.

Button Arrow down (2)
- ▶ Press and hold button: Belts of electric lift move downward.
- ▶ Release button: Electric lift stops lowering process.

9.2 Electric lift

Warning

Danger of injury due to not using a wheelchair!
When lifting up or sitting the user down:
- ▶ Always position wheelchair directly behind user.
- ▶ Lock brakes of wheelchair.

Note *A pelvic support set for additional safety is always required when using the electric lift.*

The electric lift permits simple and comfortable verticalisation/straightening for high-dependency or overweight users.

- ▶ Do not use electric lift of THERA-Trainer balo continuously.
- ▶ Maximum 10 lifts within 5 minutes when loaded.

Starting up the electric lift

- ▶ Plug power plug into socket outlet.
- ▶ Switch on electric lift with ON-/OFF-button.
- ▶ Make sure that SAFETY-STOP button is unlocked.

Green LED is on.

- ▶ Check if SAFETY-STOP button is functional.
- ▶ Unlock SAFETY-STOP button.

THERA-Trainer balo is ready for use.

Applying the patient belt with leg straps and bottom enlarged

Use electric lift exclusively in combination with a patient belt. **Note**

The patient belt is equipped with two removable leg straps which prevent the patient belt from slipping.

Applying the patient belt:

The patient belt with leg straps and bottom enlarged is available in 4 different sizes. **Note**

- ▶ Select patient belt size to fit the user's abdominal girth.
- ▶ Bend the upper body of the user forward in his wheelchair.
- ▶ Place base **1** (bottom edge) of patient belt safely between buttocks and wheelchair seat.
- ▶ Lean the user back and close abdominal belt.
- ▶ Make sure that user is sitting on base **1** (bottom edge) of patient belt.
- ▶ If necessary, put both leg straps around the user's legs and fix them on the patient belt with velcro straps.

Controlling the electric lift via control unit

To lift the user:

▶ Press button **Arrow down** on control unit.

Belts move down.

▶ Pull down right and left belt.
▶ Close patient belt by putting buckle tongues into buckles.
▶ Make sure that buckle tongues audibly click into place.
▶ Make sure that base of patient belt is under the user's buttocks.
▶ Press button **Arrow up** on control unit.

The electric lift slowly lifts the user.

To lower the user:

▶ Press button **Arrow down** on control unit.

The electric lift slowly lowers the user.

▶ Open patient belt by pulling buckle tongues out of belt buckles.
▶ Press button **Arrow up** on control unit.

Belts move up.

▶ Remove patient belt from user.

Controlling the electric lift via sip-and-puff control

▶ Plug provided sip-and-puff hose into electric lift.

To lift the user:

▶ Blow air into sip-and-puff hose.

Belts move down.

▶ Pull down right and left belt.
▶ Close patient belt by putting buckle tongues into buckles.
▶ Make sure that buckle tongues audibly click into place.
▶ Make sure that base (bottom edge) of patient belt is under the user's buttocks.
▶ Suck air out of sip-and-puff hose.

The electric lift slowly lifts the user.

To lower the user:

▶ Blow air into sip-and-puff hose.

The electric lift slowly lowers the user.

▶ Open patient belt by pulling buckle tongues out of belt buckles.
▶ Suck air out of sip-and-puff hose.

Belts move up.

▶ Remove patient belt from user.

9.3 Lifting and lowering without electric lift

Warning

Danger of injury due to faulty fuse!

▶ Make sure that the ball catch pin goes completely through both holes when applying the pelvic support set.

Warning

Danger of injury due to not using a wheelchair!

When lifting up or sitting the user down:

▶ Always position wheelchair directly behind user.

▶ Lock brakes of wheelchair.

Note

If necessary, lift or lower the user without the electric lift with the help of an assistant who is trained for the process.

To lift the user:

▶ Set height (see 8.1 Preparation for training)
  – of knee supports
  – of table unit
  – of handrails

▶ Before starting the training session, make sure that transport castors with brake are locked.

▶ Move user directly behind THERA-Trainer balo in a wheelchair.

▶ Secure wheelchair to prevent it from moving.

▶ Put the user's feet on tread of THERA-Trainer balo and secure them (see 8.1 Preparation for training).

▶ Position knees in knee supports.

▶ Lift the user and stand him into the training position.

▶ Apply pelvic support and secure the user (see 8.1 Preparation for training).

To lower the user:

▶ Move wheelchair directly behind THERA-Trainer balo.

▶ Remove pelvic support set from user.

▶ Seat user in wheelchair.

▶ Remove the user's feet from the tread of THERA-Trainer balo.

9.4 Starting up the control and display unit

The control and display unit supports goal-oriented training with biofeedback illustrations.

Note *Use control and display unit with 10.4” or 23” colour screen exclusively with software package Balancing individual therapy, position sensor and holder.*

- ▶ Switch on control and display unit.
- ▶ Operate control and display unit via touch soft keys.
- ▶ Observe the enclosed user manual.

Adjusting the mobile holder

Note *Mobile holder is suitable for control and display unit with 23” colour screen.*

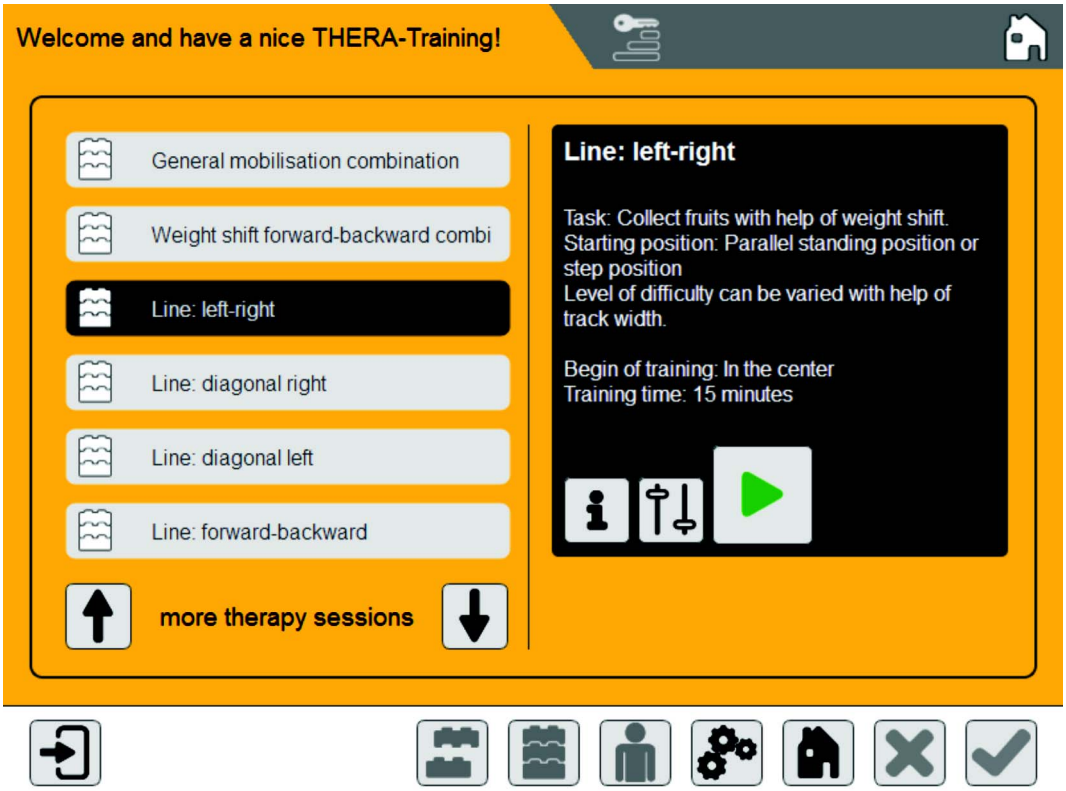
- ▶ Set mobile holder individually to
  - – correct height.
  - – correct tilt.
  - – correct distance.
- ▶ Before starting the training session, make sure that transport castors with brake are locked.
- ▶ Observe the enclosed user manual.

Adjusting the table holder

Note *Table holder is suitable for control and display unit with 10.4” colour screen.*

- ▶ Set table holder individually to correct tilt.
- ▶ Before every training session, make sure that metal support foot is in optimal training position.
- ▶ Observe the enclosed user manual.

Setting the software package Balancing individual therapy


Welcome and have a nice THERA-Training!
General mobilisation combination
Weight shift forward-backward combi
Line: left-right
Line: diagonal right
Line: diagonal left
Line: forward-backward
more therapy sessions
Line: left-right
Task: Collect fruits with help of weight shift.
Starting position: Parallel standing position or step position
Level of difficulty can be varied with help of track width.
Begin of training: In the center
Training time: 15 minutes

Functions:

- ❑ it is possible to choose between several therapy sessions/biofeedback illustrations
- ❑ quick start with 2 buttons is possible
- ❑ up to 5 training parameters per training session can be set (e.g. coordination, training time, etc.)
- ❑ It is also possible to configure one's own individual training sessions from pre-set modules.

▶ Observe the enclosed user manual.

10 CLEANING AND DISINFECTION

Danger

Danger to life due to electric shock!

- ▶ Prior to any cleaning or disinfection, switch off electric lift.
- ▶ Prior to any cleaning or disinfection, unplug the power plug of the electric lift.
- ▶ Make sure that no cleaning agent or disinfectant gets into the THERA-Trainer balo
- ▶ If any cleaning agent or disinfectant gets into the THERA-Trainer balo, contact a trained dealer immediately.

Warning

Risk of infection due to contaminated accessories/options!

- ▶ Wear gloves for cleaning and disinfection.

Caution

Material damage due to incorrect cleaning or disinfection!

- ▶ Never use cleaning agents that are aggressive, abrasive or caustic, or contain solvents.
- ▶ Never use cleaning agents that contain alcohol, cleaning solvent or ammonia.
- ▶ Use exclusively mild and environment-friendly cleaning agents and disinfectants.
- ▶ Use exclusively disinfectants that conform to country-specific regulations.
- ▶ Observe safety instructions by manufacturers of cleaning agents and disinfectants.

Clean/disinfect THERA-Trainer balo as follows:

- ▶ Switch off electric lift and pull power plug.
- ▶ Pull power plug of control and display unit.
- ▶ Check electronic components for damage.
  - – If any damage is found, do not clean but contact trained dealer.
- ▶ Clean surface of THERA-Trainer balo with a soft damp cloth.
- ▶ Clean foils and stickers with care.
- ▶ To clean surfaces of THERA-Trainer balo, use exclusively disinfectants approved in accordance with country-specific directives.
- ▶ Allow THERA-Trainer balo to dry.

Disinfecting the sip-and-puff hose:

- ▶ Put sip-and-puff hose into a disinfectant solution suitable for medical instruments.
- ▶ Disinfect sip-and-puff hose before every use.
- ▶ Replace sip-and-puff hose if damaged.
- ▶ Replace sip-and-puff hose after 30 disinfections at the lastest.

11 MAINTENANCE AND REPAIR

11.1 Replacing the balance unit

Note

According to the manufacturer's specifications, the balance unit of the THERA-Trainer balo must be replaced after five years.

11.2 Replacing the patient belt with leg straps and bottom enlarged

Note

According to the manufacturer's specifications, the patient belt with leg straps and bottom enlarged on the THERA-Trainer balo must be replaced after 5 years.

11.3 Replacing the fuse

(1) Fuse slot

Caution

Material damage due to incorrect fuse!

▶ Use exclusively fuses recommended by the manufacturer (siehe 12 Technical data).

Fuse type

Fuse used:

❑ 2 x 2A slow-acting highbreak (e.g. Littelfuse series 215.002P)

Replace fuse as follows:

▶ Make sure that electric lift is without power.
▶ Open fuse slot on motor housing **1**.
▶ Pull out fuse holder.
▶ Replace defective fuse with new fuse (siehe 12 Technical data).
▶ Push fuse holder into fuse slot.
▶ Close fuse slot **1**.

11.4 Further use

The THERA-Trainer balo is suitable for further use by a different customer.

Before every further use of the THERA-Trainer balo

▶ Clean and disinfect thoroughly (see 10 Cleaning and disinfection).
▶ Replace all cushions, velcro straps and the patient belt with leg straps and bottom enlarged.
▶ Make sure that all accessories and options are at hand (see delivery note).
▶ Perform a safety inspection by way of a visual check or a functional check.
▶ Ask the manufacturer for the service instructions for safety control.

12 TECHNICAL DATA

THERA-Trainer balo	
Dimensions: ❑ with balance unit long ❑ with balance unit short	l x w x h 118 cm x 78 cm x 95-125 cm 118 cm x 78 cm x 77-98 cm
Weight: ❑ with balance unit long ❑ with balance unit short	 77 kg - 101.5 kg 75 kg - 99.5 kg
Power supply for electric lift	230 V~, 50/60 Hz
Fuses	2 x 2A slow-acting
Medical device class	I
Protection class: ❑ THERA-Trainer balo	 II
Degree of protection	Type BF
Protection category	IP2X
Sound emission	LpA < 45 dB(A)
Ambient conditions for use	5 °C to 40 °C 5% to 93% Rh 700 to 1,060 hPa
Ambient conditions for Transport/delivery	-25 °C to 70 °C 5% to 93% Rh 700 to 1,060 hPa
suitable for users with body size: ❑ with balance unit long ❑ with balance unit short suitable for users with body weight: ❑ with balance unit long ❑ with balance unit short	 150 cm to 200 cm 120 to 160 cm up to 140 kg up to 140 kg
Materials used	steel, stainless steel, aluminium, rubber, plastics (POM, PA6, ABS, PE), wood
Economic life-time THERA-Trainer balo:	10 years

13 STANDARDS AND LAWS

The THERA-Trainer balo conforms to the following standards:

- ❑ MDD 93/42 EEC
- ❑ Machinery directive 2006/42 EC
- ❑ DIN EN 60601-1
- ❑ DIN EN 60601-2
- ❑ DIN EN 12182
- ❑ DIN EN ISO 13485

14 DISPOSAL

To dispose of the THERA-Trainer balo:

- ▶ Observe country-specific regulations and specifications.
- ▶ Dispose of metal parts as scrap metal.
- ▶ Dispose of plastic parts as prescribed, depending on the type of material.
- ▶ Dispose of electric and electronic components as electronic scrap.

15 NOTES ON ELECTROMAGNETIC COMPATIBILITY

15.1 Lines, line lengths and accessories

The electric lift of the THERA-Trainer balo is to be exclusively used with the original supply cable.

15.2 Warning notice regarding installation

The electric lift is not to be used in the immediate vicinity of or stacked with other devices. If it is necessary that the device or system be used next to or in a stack with other devices, one should observe the electric lift to check if the arrangement permits it to work as intended.

15.3 Level of conformity

The immunity level requirements of IEC 60601 are met.

15.4 Electromagnetic emission

<table>
<tr><th colspan="3">Directives and manufacturer's declaration - Electromagnetic emissions</th></tr>
<tr><td colspan="3">The electric lift is designed for operation in an electromagnetic environment as described below. The customer or the user of the electric lift should make sure that the unit is used in such an environment.</td></tr>
<tr><td>Emission measurement</td><td>Compliance</td><td>Directive for electromagnetic environment</td></tr>
<tr><td>HF emissions according to CISPR 11</td><td>Group 1</td><td>The electric lift uses HF energy exclusively for internal functions. This incurs very low HF emissions so it is unlikely to interfere with any nearby electronic devices.</td></tr>
<tr><td>HF emissions according to CISPR 11</td><td>Class B</td><td rowspan="3">The electric lift is designed for use in various facilities, including:
❑ Residential buildings
❑ Facilities that are directly connected to a public mains supply which also supplies residential buildings.</td></tr>
<tr><td>Harmonics according to IEC 61000-3-2</td><td>Class A</td></tr>
<tr><td>Voltage fluctuation/flicker according to IEC 61000-3-3</td><td>met</td></tr>
</table>

15.5 Immunity

Directives and manufacturer's declaration - Immunity to electromagnetic disturbance			
The electric lift is designed for operation in an electromagnetic environment as described below. The customer or the user of the electric lift should make sure that the unit is used in such an environment.			
Immunity test	EC 60601 test level	Level of conformity	Directive for electromagnetic environment
Static discharge (ESD) according to IEC 61000-4-2	± 6 kV contact discharge (indirect) ± 8 kV air discharge	± 6 kV contact discharge ± 8 kV air discharge	Floors should be wooden, concrete or ceramic tiled. If the floor contains synthetic materials, the relative air humidity must be at least 30%.
Fast transient electrical disturbances/ bursts according to IEC 61000-4-4	± 2 kV for supply lines ± 1 kV for input and output lines	± 2 kV for supply lines ± 1 kV for input and output lines	The quality of the supply voltage should correspond to that of a typical business or hospital environment.
Surges according to IEC 61000-4-5	± 1 kV differential mode voltage (symmetrical) ± 2 kV common mode voltage (asymmetrical)	± 1 kV differential mode voltage (symmetrical) ± 2 kV common mode voltage (asymmetrical)	The quality of the supply voltage should correspond to that of a typical business or hospital environment.
Voltage dips, short interruptions and fluctuations of the supply voltage according to IEC 61000-4-11	< 5 % U_T for 0.5 periods (> 95 % dip) 40 % U_T for 5 periods (60% dip) 70 % U_T for 25 periods (30% dip) < 5 % U_T for 5 s (> 95% dip)	< 5 % U_T for 0.5 periods (> 95 % dip) 40 % U_T for 5 periods (60% dip) 70 % U_T for 25 periods (30% dip) < 5 % U_T for 5 s (> 95% dip)	The quality of the supply voltage should correspond to that of a typical business or hospital environment. If the user of the electric lift requires continuous functioning in case of power supply interruptions, we recommend using a non-interruptible power system or a battery to supply the electric lift.
Magnetic field at supply frequency (50/60 Hz) according to IEC 61000-4-8	3 A/m	3 A/m	Magnetic fields at mains frequency should correspond to the typical values for business and hospital environments.

NOTE: U_T is the supply AC voltage before the test level is applied.

Directives and manufacturer's declaration - Immunity to electromagnetic disturbance			
The electric lift is designed for operation in an electromagnetic environment as described below. The customer or the user of the electric lift should make sure that the unit is used in such an environment.			
Immunity test	EC 60601 test level	Level of conformity	Directive for electromagnetic environment
Conducted HF emissions according to IEC 61000-4-6 Radiated HF emissions according to IEC 61000-4-3	3 V_{eff} 150 kHz to 80 MHz 3 V/m 80 MHz to 2.5 GHz	3 V_{eff} 3V/m	Portable and mobile radio equipment should not be used closer to the electric lift (including line) as the protective distance recommended. The equation for the transmission frequency in question is used to calculate it. **Recommended protective distance:** $d = [3.5/3] * \sqrt{P} = 1.17 * \sqrt{P}$ $d = [3.5/3] * \sqrt{P} = 1.17 * \sqrt{P}$ for 80 MHz to 800 MHz $d = [7.0/3] * \sqrt{P} = 2.33 * \sqrt{P}$ for 800 MHz to 2.5 GHz with P as the transmitter's power rating in Watts (W) according to the indications of the transmitter manufacturer and d as the recommended protective distance in metres (m). An on-site test should show that the field intensity of stationary radio transmitters are below the compliance level with all frequencies. Disturbances are possible in the vicinity of equipment labelled as follows.

NOTE 1: For 80 MHz and 800 MHz, the higher frequency range applies.

NOTE 2: These guidelines may not be applicable in every case. Buildings, objects and persons influence the propagation of electromagnetic waves by absorption and reflection.

An exact technical estimate of the field intensity of stationary transmitters such as base stations of mobile phones and land mobile radio devices, amateur radio stations, AM and FM radio broadcast and television stations is not possible. In order to determine the electromagnetic environment with regard to stationary transmitters one should consider a survey of the location. If the field intensity measured at the location where the electric lift will be used exceeds the conformity levels listed above, one should observe the electric lift in order to check if it is working correctly and as intended. Should any performance irregularities occur, it might be necessary to take additional measures such as modifications to the THERA-Trainer balo or a change of locations.

In the frequency range between 150 kHz and 80 MHz, the field intensity should be below 3 V/m.

15.6 Recommended protective distances between portable and mobile HF telecommunication devices and THERA-Trainer balo

The electric lift is designed for operation in an electromagnetic environment as described below. The customer or the user of the electric lift can help to prevent electromagnetic disturbances by observing the minimum distance between portable and mobile HF telecommunication devices (transmitters) and the electric lift as indicated below (depending on the output power of the telecommunication device).			
Power rating of transmitter [W]	Protective distance depending on transmission frequency [m]		
	150 kHz to 80 MHz	80 MHz to 800 MHz	800 MHz to 2.5 GHz
	$d = 1.17 \sqrt{P}$	$d = 1.17 \sqrt{P}$	$d = 2.33 \sqrt{P}$
0.01	0.12	0.12	0.23
0.1	0.37	0.37	0.74
1	1.17	1.17	2.33
10	3.7	3.7	7.37
100	11.7	11.7	23.30

The distance for any transmitters the nominal power of which is not indicated in the table above can be determined by means of the equation given. P is the nominal power of the transmitter in Watts (W) as indicated by the transmitter manufacturer.

NOTE 1:

An additional factor 10/3 was used for calculating the recommended protective distance for transmitters in the frequency range between 80 MHz and 2.5 GHz. This reduces the probability of a mobile/portable communication device that was brought to the patient area by mistake causing a disturbance.

NOTE 2:

These guidelines may not be applicable in every case. Buildings, objects and persons influence the propagation of electromagnetic waves by absorption and reflection.

16 WARRANTY

In accordance with legal regulations, the manufacturer grants a manufacturer's warranty for the THERA-Trainer balo if it is handled with due care. The basis is the date of delivery.

Within this period of time, the manufacturer will replace free of charge any faulty parts of the THERA-Trainer balo or repair free of charge the THERA-Trainer balo in the factory or an authorised workshop.

Excluded from manufacturer's warranty:

- ❑ Wear parts
- ❑ Opened devices
- ❑ Unauthorised accessories or external devices
- ❑ Devices repaired by persons other than trained dealers.
- ❑ Any damage due to incorrect use.

NOTES

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For declarations of conformity, see www.thera-trainer.de